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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,150	07/25/2001	Gary R. DelDuca	47097-01080	6442
30223	7590	08/02/2005	EXAMINER	
JENKENS & GILCHRIST, P.C. 225 WEST WASHINGTON SUITE 2600 CHICAGO, IL 60606			MADSEN, ROBERT A	
			ART UNIT	PAPER NUMBER
			1761	

DATE MAILED: 08/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/915,150

Applicant(s)

DELDUCA ET AL.

Examiner

Robert Madsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37,87-90 and 161-171 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37,87-90 and 161-171 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>December 27, 2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 10, 2005 has been entered. Claims 1-37, 87-90, 161-171 remain pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-37, 87-90, 161-171 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. The term "turns brown in a natural time period" in claims 1, 22, 161 is a relative term which renders the claim indefinite. The term "turns brown in a natural time period" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. First, it is not clear if "turns brown" means *any* brown is visible or 100% brown. Second, it is not clear if "a natural time period". For examination purposes, it will be understood that the term "turns brown in a

natural time period" means the meat remains red for the conventional period of up to 3 days after being removed from a modified atmosphere package and exposed to air.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
6. Claims 1-6,8-11,13-26,28-30,32-37,87-90,161,162,164-171 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carr et al. (US 6054153) in view of Woodruff et al. (US 4522835) and Koch et al. (US 3459117) and Shaklai (US 6042859).
7. Carr et al. teach a method of manufacturing a modified atmosphere meat package comprising a first package made of a polystyrene foam tray sealed by a permeable pvc overwrap as recited in claims 16,17 and 35, covering the first package with a second impermeable package such that a pocket is formed between the two packages, flushing the pocket, as recited in claims 8,28,164 with gases consisting essentially of about 30% carbon dioxide and about 70% nitrogen, as recited in claims 9-11,29,30 in order to lower the level of oxygen in the pocket to preferably less than 0.5%, as recited in claims 5, 6,25,26,165,166 to prevent the formation of metmyoglobin, as recited in claims 1,22, and 161. Additionally, Carr et al. teach flushing alone may not reduce the level of oxygen to less than 0.5%, which would be evident by the formation of oxymyoglobin as recited in claim 22, and teach placing an oxygen scavenger and accelerator in the pocket to reduce the level about zero percent in less than 24 hours, as recited in claims 2-4,23,24,162. Carr et al. further teach removing the

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second package, which would modify the packages atmospheres and would not destroy the first package, before retailing to allow the raw meat to be exposed to ambient atmosphere to give the meat the same color as fresh meat as recited in claims 13-15,32-34,87-90,167-171 (Abstract, Column 1, line 46 to Column 2, line 45,Column 3, lines 47-67,Column 5, line 60 to Column 6, line 49).

8. However, Carr et al. are silent in teaching 0.1-0.8%,0.3-0.5% , or 0.1-0.5%, carbon monoxide in addition to the carbon dioxide and nitrogen to form carboxymyoglobin, as recited in claims 1, 11, 18-21,30,36,37,161 or convert deoxymyoglobin directly to carboxymyoglobin as recited in claim 1 or oxymyoglobin to carboxymyoglobin as recited in claim 22, wherein the CO is associated with the raw meat within the first package is adapted to be removable so that the meat browns in a natural time period, as recited in claims 1,22, and 161.

9. Woodruff et al. , who also is concerned with the color of meat during storage in a low oxygen atmosphere, teaches storing a meat with a gas mixture that includes carbon monoxide (0.1-3% CO, along with 20-60% CO₂ , 40-80% N₂ , and 0% O₂) to maintain a desired red color. At this particular level of CO, Woodruff et al. teach only the first 0.25 inch of the meat undergo a conversion of deoxymyoglobin to carboxymyoglobin. Woodruff et al. also teach the meat is stored in these conditions prior to final sale/consumption packaging. (Abstract, Column 1, line 63 to Column 3, line 30, Examples).

10. Koch et al., also like Carr et al., are concerned with providing a red-colored meat at the retail outlet. Koch et al. teach wrapping a meat with CO containing film under a

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modified atmosphere, so that the carbon CO is transferred from the film to contact the surface of the meat so that carboxymyoglobin is formed on the meat surface(Column 1, lines 23-50, Column 2, line 67 to Column 3, line3, Column 3, line 49 to column 4, line 10). Koch et al. teach a meat surface that has been exposed to CO for 7 days during storage under a modified atmosphere will remain red in color for 3 days after being removed from the modified atmosphere packaged and packaged in conventional wrapper at the retail outlet (Column 3, lines 4-16). Thus, Koch et al. provide evidence that CO is removably associated with a meat surface so that the meat browns in a natural time period because the meat has a shelf life of 3 days after being removed from the modified atmosphere package and placed in a conventional display wrapper.

11. Shaklai is relied on as evidence that the color of meat pigment exposed to CO is *not* fixed the meat surface and that the meat surface will brown upon exposure to air depending on the time the meat is exposed to the CO (Column 8, lines 10-30). In Example 2, Shaklai teaches after storage for 30 minutes to CO, the meat became brown within 24 hours after exposure to air, which is "within a natural time period" since meat general may take up to 3 days after exposure to the air to brown. In Example 4, Shaklai also teaches that when meat is preserved in a 100% CO environment for 21 days so that the entire meat becomes red, the outer 1mm eventually becomes brown in 14 days after removing the meat from the CO enriched environment and exposing the meat to air (Example 4 in light of Example 3 in Column 9).

12. Therefore, it would have been obvious to modify Carr et al. and include anywhere from 0.1-0.8% carbon monoxide, 40-80% nitrogen, and 20-60% carbon dioxide in the

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modified atmosphere pocket (i.e. between the two packages) to convert the deoxymyoglobin to carboxymyoglobin and convert to oxymyoglobin and then metmyoglobin to brown in a natural time period when exposed to air depending on the particular time in stored in the modified atmosphere, as recited in claims 1,11,18-22,30, 36, 37 and 161, since Woodruff et al. teach low/no oxygen modified atmosphere including CO will turn the surface of the meat red in color (i.e. affects the first 0.25 in.) at a composition of 0.1-0.8% carbon monoxide , 40-80% nitrogen and 20-60% carbon dioxide, Koch et al. teach contacting the surface of a meat in a modified atmosphere with CO to contact the surface of the meat will brown in a natural period (i.e. the red color remains for only 3 days after 7 days of storage) after removal from a modified atmosphere package, and Shaklai teaches the time it takes for a meat surface to brown after removal from storage with CO depends on the time the meat is stored with CO. One would have been substituting one conventional carbon dioxide/ nitrogen based atmosphere for another for the same purpose: providing a low/no oxygen atmosphere for providing the appearance of fresh cut meat after storage. Forming carboxymyoglobin from deoxymyoglobin or oxymyoglobin would have been obvious depending on the level of oxygen in the modified atmosphere since Carr et al. teach some oxygen may be present during the first 24 hours.

13. Claims 1,2,5-10,12-15,18-23,25-29,31-34,36,37,87-90,161-171 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breen et al. (US 5711978) in view

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of Woodruff et al. (US 4522835) and Koch et al. (US 3459117) and Shaklai (US 6042859) and Verbruggen (DE 1935566 A).

14. Breen et al. teach a method of packaging meat in a modified atmosphere package for sale/consumption comprising supplying a first package comprising a sealed tray, surrounding the tray with a bag, removing oxygen by vacuum, supplying/flushing the bag, as recited in claims 7,8,27,28,163,164 with substantially pure carbon dioxide gas, as recited in claims 9,10,12,28,29, 31,165,166, and sealing the bag such that oxygen is at 30-50 ppm in the pocket, equilibrating within minutes to 250 ppm and eventually drops off significantly as the meat absorbs the oxygen, as recited in claims 5,6,25,26, which would in turn form oxymyoglobin as recited in claims 18, 22 prevent the formation of metmyoglobin, as recited in claims 1,22, and 161, and due to the lack of oxygen in the package result in the formation of deoxymyoglobin as recited in claims 19. Additionally, Breen et al. teach at least a portion of bag can be removed for retailing without destroying the tray to expose the meat to ambient atmosphere, as recited in claims 13-15,32-34,87-90,167-171, As an extra measure of safety, Breen et al. further teach adding an oxygen scavenger in the pocket, as recited in claims 2,23,162(Figure 7, Column 2, lines 27-62, Column 4, lines 40-63, Column 5, line 5 to Column 6, line 5). However, Breen et al. are silent in teaching 0.1-0.8%,0.3-0.5%, or 0.1-0.5%, carbon monoxide in addition to the substantially pure carbon dioxide, as recited in claims 1, 12,18-22,31,36,37,161 or convert deoxymyoglobin directly to carboxymyoglobin as recited in claim 1 or oxymyoglobin to carboxymyoglobin as recited in claim 22, wherein

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the CO is associated with the raw meat within the first package is adapted to be removable, as recited in claims 1,22, and 161.

15. Woodruff et al. , who also is concerned with the color of meat during storage in a low oxygen atmosphere, teaches storing a meat with a gas mixture that includes carbon monoxide (0.1-3% CO, along with 20-60% CO₂ , 40-80% N₂ , and 0% O₂) to maintain a desired red color. At this particular level of CO, Woodruff et al. teach only the first 0.25 inch of the meat undergo a conversion of deoxymyoglobin to carboxymyoglobin. Woodruff et al. also teach the meat is stored in these conditions prior to final sale/consumption packaging. (Abstract, Column 1, line 63 to Column 3, line 30, Examples).

16. Koch et al., like Breen et al., are concerned with providing a red-colored meat at the retail outlet. Koch et al. teach wrapping a meat with CO containing film under a modified atmosphere, so that the carbon CO is transferred from the film to contact the surface of the meat so that carboxymyoglobin is formed on the meat surface(Column 1, lines 23-50, Column 2, line 67 to Column 3, line3, Column 3, line 49 to column 4,line 10). Koch et al. teach a meat surface that has been exposed to CO for 7 days during storage under a modified atmosphere will remain red in color for 3 days after being removed from the modified atmosphere packaged and packaged in conventional wrapper at the retail outlet (Column 3, lines 4-16). Thus, Koch et al. provide evidence that CO is removably associated with a meat surface so that the meat browns in a natural time period because the meat has a shelf life of 3 days after being removed from the modified atmosphere package and placed in a conventional display wrapper.

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17. Shaklai is relied on as evidence that the color of meat pigment exposed to CO is *not* fixed the meat surface and that the meat surface will brown upon exposure to air depending on the time the meat is exposed to the CO (Column 8, lines 10-30). In Example 2, Shaklai teaches after storage for 30 minutes to CO, the meat became brown within 24 hours after exposure to air, which is "within a natural time period" since meat general may take up to 3 days after exposure to the air to brown. In Example 4, Shaklai also teaches that when meat is preserved in a 100% CO environment for 21 days so that the entire meat becomes red, the outer 1mm eventually becomes brown in 14 days after removing the meat from the CO enriched environment and exposing the meat to air (Example 4 in light of Example 3 in Column 9).

18. Verbruggen is relied on as further evidence of the conventionality of utilizing a carbon dioxide and carbon monoxide gas mixture for preserving meat (See Abstract).

19. Therefore, it would have been obvious to modify Breen et al. and include anywhere from 0.1-0.8% carbon monoxide, 40-80% nitrogen, and 20-60% carbon dioxide in the modified atmosphere pocket (i.e. between the two packages) to convert the deoxymyoglobin to carboxymyoglobin and convert to oxymyoglobin and then metmyoglobin to brown in a natural time period when exposed to air depending on the particular time in stored in the modified atmosphere,, as recited in claims 1,11,18-22,30, 36, 37 and 161, since Woodruff et al. teach low/no oxygen modified atmosphere including CO will turn the surface of the meat red in color (i.e. affects the first 0.25 in.) at a composition of 0.1-0.8% carbon monoxide, 40-80% nitrogen and 20-60% carbon dioxide, Koch et al. teach contacting the surface of a meat in a modified atmosphere

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with CO to contact the surface of the meat will brown in a natural period (i.e. the red color remains for only 3 days after 7 days of storage) after removal from a modified atmosphere package, and Shaklai teaches the time it takes for a meat surface to brown after removal from storage with CO depends on the time the meat is stored with CO. One would have been substituting one conventional carbon dioxide/ nitrogen based atmosphere for another for the same purpose: providing a low/no oxygen atmosphere for providing the appearance of fresh cut meat after storage. Forming carboxymyoglobin from deoxymyoglobin or oxymyoglobin would have been obvious depending on the level of oxygen in the modified atmosphere since Breen et al. teach some oxygen may be present during the first 24 hours.

Response to Amendment

20. The Declaration under 37 CFR 1.132 filed May 10, 2005 by Mr. Gary DelDuca is insufficient to overcome the rejection of claims because the prior art does indeed teach a browning in a "natural time period". For example, Koch et al. teach the meat is red for a total of 10 days: 7 days in contact with CO-containing wrapper, followed by 3 days without contact with CO. As discussed in the rejections above, the conventional meat after removal from a modified atmosphere package remains red for up to 3 days. Additionally, Shaklai teaches in Example 2, meat exposed to CO after 30 minutes will turn brown within 24 hours, and further teaches the period at which the meat turn brown depends on the time stored with CO (Column 8, lines 10-30). Thus, two references cited (e.g. Shaklai and Koch et al.) teach the meat browns as expected in a normal

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atmosphere within 3 days after being stored within in either a high level or low level CO-environment. One would expect that at the levels taught by Woodruff , 0.1-3% CO, and the depth of CO saturation taught by Woodruff, 0.25 in, that the meat would brown in a natural time period, depending on the time the meat was stored with the CO when exposed to room air. Thus, one would expect that meat stored in the packages of Carr et al. or Been et al., combined with the modified atmosphere of Woodruff to turn brown in a natural time period , depending on the time stored with the CO. In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Response to Arguments

21. Applicant's arguments with respect to the rejections have been fully considered but they are not persuasive.

22. Applicant contend that the prior art considered that CO fixed the color of the meat pigment based on the FDA regulatory laws and references such as Sorheim. While CO was not allowed in meat storage since at least 1962 in the US, this is not relevant to the issue of obviousness in this case because Patent law is independent from FDA regulatory law. This issue often is discussed with respect to the determination of pharmaceutical utility (MPEP 2107.01: Section V.): "FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws." In re Brana, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995) (citing Scott v. Finney, 34 F.3d 1058, 1063, 32 USPQ2d 1115, 1120 (Fed. Cir.1994)). Furthermore, it is noted that the


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US Patents cited in the Office action, such as Woodruff, illustrate that Patent law is independent from FDA regulatory law. Additionally, as discussed in the rejections above, Koch et al. teach browning in a natural time period (i.e. up to 3 days) red color remains 3 days after exposing a meat surface to CO for 7 days. Additionally, Shaklai teaches red color remains for 24 hours after exposure to CO for 30 minutes, and that the time period that the red color remains depends on the time the meat is exposed to the CO. Thus, the art of record does show that meat exposed to CO will brown within a natural period, depending on the level of CO and time exposed.

Conclusion


23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Madsen whose telephone number is (571) 272-1402. The examiner can normally be reached on 8:00AM-4:30PM M-F.

24. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (571) 272-1398. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


MILTON I. CANO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700

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25. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert Madsen 
Examiner
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